

Appl. No. : 09/579,327
Filed : May 25, 2000



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Rejections under 35 U.S.C. §112, second paragraph.

The examiner has rejected claims 1-14 because the Examiner believes that the term "acceptable pH" is vague. However, the real term is a "physiologically acceptable pH". One of skill in the art would know that a physiologically acceptable pH would depend on the method and site of administration. For example, an intravenous administration would require a pH of about 7.0 (see Examples 1 and 2), while an oral administration would require a pH of about 1.5 to 2.5 or more. Claims 13 and 21 have been amended to specify that TCA is trichloroacetic acid.

Rejections under 35 U.S.C. §102(b).

The examiner has rejected claims 1-4, 6, 8-9 and 14 under 35 U.S.C. §102(b) as being anticipated by Matsuzaki, et al. However, the presently claimed invention is a method for making peptidoglycan extracts by treating them with an acid, such as trichloroacetic acid. In contrast, Matsuzaki, et al. teaches making the peptidoglycan extracts using the cell wall lytic enzyme, achromopeptidase, a very specific protein. Therefore, the claims are not anticipated by Matsuzaki, et al. because Matsuzaki, et al. does not teach using acid to produce the cell wall extracts.

Rejections under 35 U.S.C. §103(a).

The Examiner has rejected Claims 1, 11-12, 16, and 19 as being unpatentable over Matsuzaki, et al in view of Converse et al. As explained in the 102 rejection above, Matsuzaki et al. teaches producing peptidoglycan extracts using achromopeptidase, an enzyme. Converse et al. teaches a method of removing lipids using chloroform. Therefore, the references taken alone or together do not teach all of the claim elements because they do not teach using acid to produce the cell wall (or peptidoglycan) extracts.

Rejections under 35 U.S.C. §103(a).

The Examiner has rejected Claims 1, 4-5, 7, 10, 13, 15-17, and 20-21 as being unpatentable over Matsuzaki, et al in view of Converse et al. and further in view of Roe et al. As mentioned above, neither Matsuzaki et al, nor Converse et al. teach using an acid to produce a cell wall extract. Roe et al. teaches standard techniques used in protein purification, such as heat treatment, and denaturation with strong acids such as acetic acid and TCA. However, the acid treatment used in the present invention is for production of an immunologically active extract by hydrolyzing the peptidoglycan bonds, not for the purposes of purification and thus, the above

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references taken alone or together do not teach using acid to produce the cell wall extracts and there is no *Prima facie* showing of obviousness.

In addition, even if the above references taught all of the claimed elements, there is no suggestion that using an acid would have the same effect that a specific enzyme would have on the cell wall extracts. Therefore, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §103(a).

Conclusion

In view of the above amendments and arguments, Applicants believe the above-identified patent application is in condition for allowance. Should there be any questions, the Examiner is respectfully requested to contact the undersigned attorney at the telephone number appearing below. Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

13. (Amended) The method of Claim 1 further comprising [TCA] trichloroacetic acid precipitation of said remaining solution.

21. (Amended) The method of Claim 16 further comprising [TCA] trichloroacetic acid precipitation from said remaining solution.

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